

REMARKS

Applicants respectfully thank the Examiner for finding the previous amendment persuasive and withdrawing the previous rejections.

Claim 1 has been amended to correct a typographical error and to remove linoleic acid from the list of boosters.

New claim 9 has been introduced, dependent on claim 5, directed to the retinoid boosters supported by the previously submitted Declaration.

New claim 10 has been introduced, dependent on claim 6, directed to the retinoid boosters supported by the previously submitted Declaration.

Care has been taken not to introduce any new matter.

The Present Invention

The present invention addresses the problem of providing an alternative treatment for the signs of aging by employing a unique combination of retinoid, retinoid booster, and phytoestrogen. However, it has been discovered that *boosters* and *phytoestrogens*, while boosting the benefits of retinoids, destabilize the retinoid by inducing oxidation of retinol. The present invention addresses the problem of providing a stable skin care product with maximum efficacy, by preventing any undesired interaction of the retinoid and the boosting agents and the phytoestrogens during storage, as follows:

a first composition comprising about 0.001% to about 10% of a retinoid;

a second composition comprising about 0.0001% to about 50% of at least one retinoid booster selected from the group consisting of arachidic acid, linoleic acid, myristic acid, amsacrine, carbenoxolone, glycyrrhetic acid, phosphatidyl ethanolamine, sphingomyelin, phosphatidylcholine, and mixtures thereof; and from about 0.001% to about 10% of at least one phytoestrogen selected from the group consisting of genistein, diadzein, glycitin, biochanin A, formononetin, equol, and mixtures thereof;

a first compartment for storing the first composition; and

a second compartment for storing the second composition the first and second compartments being joined together.

The Present Invention is Not Obvious under 35 USC § 103

Claims 1-2 and 5-6 were rejected under 35 USC § 103 as being unpatentable over Soares et al. in view of *Pillai et al.* (US 6,648,072).

According to the Office Action, *Soares et al.* teach a method for a skin treatment comprising a topical application regime and a respective product, and relates to separate packaging, employing retinoic acid as a second active; Claims 1-2 and 5-6, and the primary references, differ as to "phytoestrogen and retinoid booster together in the composition," "presence of retinoid, and retinoid booster, phytoestrogens, in separate compartments." *Pillai et al.* are cited to purportedly remedy this deficiency.

Applicants respectfully traverse this rejection.

Soares et al. (USPN 5,914,116) teach away from the present invention. *Soares et al.* disclose two separate containers for separating two different skin actives **for two different benefits**, with one container containing a first active providing a first benefit and the second containing a second active providing a second and different benefit. See *Soares et al.* at col. 11, lines 13-15 ("... the first and second actives and benefits being different from one another..."). Furthermore, *Soares et al.* fail to disclose phytoestrogens and retinoid used together and fail to disclose the need to separate phytoestrogens from retinoids. In contrast, the present invention is directed to two separate compositions with one intended to boost the benefit of the other. According to the present invention, the two compositions are intended to be applied simultaneously or consecutively (*as opposed to separately - one in the day and one at night*), but are

kept separately for stability reasons. Independent claim 5, as worded to relate to "first benefit", is intended to clearly convey that the specified retinoids and the phytoestrogens, although separated into two compartments, are there for the same benefit (as compared with the cited art). The first composition provides a first benefit to the skin while the second composition works to boost or enhance the effect of the first benefit.

As such, *Suares et al teach away from the present invention and fail to provide a suggestion or motivation for the particular way the compositions of the present invention are stored separately. Additionally, Applicants have presented evidence of synergies in the simultaneous use of retinoids and phytoestrogens. See Tables 4, 5 and pp. 47-49 of the Specification.*

Although Pillai et al. disclose chick pea extract and linoleic acid together, there is no suggestion or motivation to combine with retinoids, and, further, there is no suggestion or motivation to keep the retinoids separate from the chick pea extract/linoleic acid. Disclosure of cleansing compositions are not relevant to the present invention, which is directed to skin care products, i.e., leave-on products. Note, Claim 1 has been amended to exclude linoleic acid.

The concomitant employment of the claimed components

The present case is distinguishable from that cited in the Office Action. In re Kerhoven, 205 U.S.P.Q. 1069 (C.C.P.A. 1980) found it to be *prima facie* obvious to combine two known compositions, both known to be useful for the same purpose, in order to form a third composition that is to be used for the very same purpose. The idea of combining them flowed logically from their having been individually taught in the prior art. In contrast, all the components of the compositions of the present invention, are not being combined, but are selectively and advantageously kept separately *until time of application, at which time the compositions are applied together*. The claims are limited to stable skin care products and to boosting a benefit of retinoids *which are kept separately to avoid destabilization*. The combination of the references does not flow logically. Therefore, the present case is different from In re Kerhoven, and the Office Action fails to demonstrate a *prima facie* case of obviousness.

The compositions of Soares et al. are for complementary benefits, but not for the same benefit. See Claims 1 and 3-3, col. 11-12.

Nevertheless, Applicants have presented strong evidence of unexpected, synergistic results, as discussed below.

Evidence of Unexpected, Synergistic, Results Must Be Considered

Applicants do not consider that the Examiner has set forth a *prima facie* case of obviousness. Even if such a case had been set forth, applicants have demonstrated unexpected, synergistic, results. Applicants have demonstrated strong *synergies* in the combination of retinoids with phytoestrogens *and boosters*. See Specification, Tables 4 and 5 at pp. 48-49. At the same time, Applicants have demonstrated that phytoestrogens contribute to loss of stability of retinoids and therefore require a dual compartment package. See Specification, Example 5, Tables 6 and 7. These are *clear and convincing*, unexpected results, rebutting any *prima facie* case of obviousness if it had been made out.

Furthermore, Applicants have submitted a Rule 132 Declaration in support of strong synergies of retinoids with B2 and B3 boosters. In particular, the data show a more than additive effect of Glycyrrhetic acid and Phosphatidyl choline (B2) in boosting retinol activity to inhibit transglutaminase production. The accompanying Declaration supports unexpected results as claimed; particularly, in claims 2 and 6, *as well as the new claims 9 and 10*.

Dual Compartment Package is *Not* obvious According to the Present Invention

Storage of the compositions in separate containers is novel and unobvious because None of the cited documents addresses the problem of retinoid stability in the presence of phytoestrogens and/or boosters. Consequently, there is no suggestion for a person skilled in the art to try to physically separate the retinoids, the boosters, and the phytoestrogens. For example, Table 1 at page 40 of the Specification shows that glycerhetinic acid contributes to 1.6-fold and linoleic acid contributes to 3.4-fold increase in the rate of retinol loss. Absent the hindsight of Applicants' specification, there would be no suggestion or motivation for one skilled in the art to separate the retinoid and booster compositions.

In particular, none of the cited references teaches or suggests a two-part composition which contains in one part a retinoid, and in the second part a retinoid booster and a phytoestrogen. There is no teaching or suggestion of how to put these components together to achieve a stable skin care product. Suares et al. fail to teach or suggest which combinations of components are placed together and which are kept separate. *Pillai et al. fail to disclose retinoids and/or to suggest keeping chick pea extract/booster separately from retinoids.* Only with the hindsight of the present invention is this combination possible.

CONCLUSION

The Office Action has combined Pillai et al. and Soares et al. and has concluded that the claimed invention is obvious. *As discussed above*, there is no motivation to combine the references *and Applicants have presented strong evidence of unexpected and synergistic results*. Some teaching, suggestion, or incentive supporting combination of multiple references must be shown in order to prove obviousness. In re Gaiger, 815 F.2d 686 (Fed. Cir. 1987); ACS Hospital Systems, Inc. v. Montefiore Hospital, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984).

An obviousness rejection is proper only when "the subject matter as a whole would have been obvious at the time the invention was made ..." (emphasis added). 35 U.S.C. 103. Applicants respectfully submit that the Office Action has improperly chosen certain aspects of one reference and combined them with aspects of other references, without showing where the motivation is to combine them to come up with the subject matter of the present invention as a whole, within the meaning of 35 U.S.C. 103. Applicants submit that the pending claims are not obvious over the cited references, under 35 U.S.C. 103, especially in view of the present Amendment. Reconsideration and withdrawal of the rejection is respectfully requested.

Reconsideration of the rejection is respectfully requested in view of the above claim amendments and remarks.

It is respectfully requested that the application be allowed to issue.

If a telephone conversation would be of assistance, Applicant's undersigned attorney invites the Examiner to telephone at the number provided.

Respectfully submitted,



Ellen Plotkin
Registration No. 36,636
Attorney for Applicant(s)

(201) 894-2253